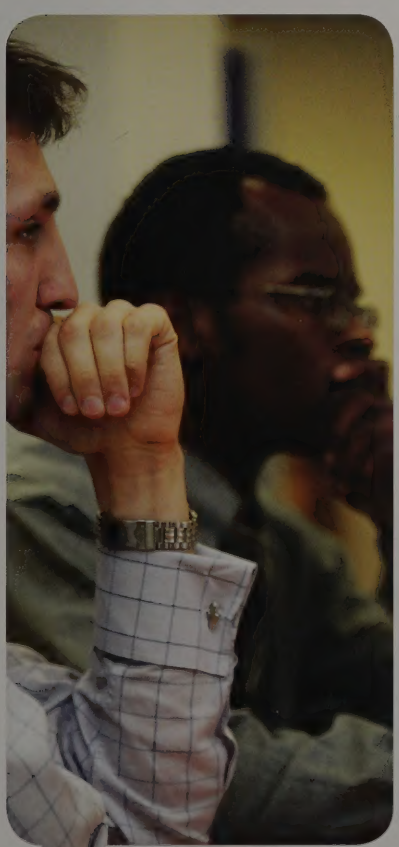
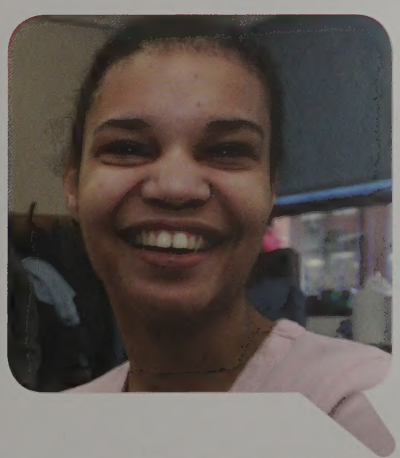
Care Quality Commission

A new start

Consultation on changes to the way CQC regulates, inspects and monitors care

June 2013





The Care Quality Commission is the independent regulator of health and adult social care in England.

Our purpose:

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role:

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

Our principles:

- We put people who use services at the centre of our work.
- We are independent, rigorous, fair and consistent.
- We have an open and accessible culture.
- We work in partnership across the health and social care system.
- We are committed to being a high performing organisation and apply the same standards of continuous improvement to ourselves that we expect of others.
- We promote equality, diversity and human rights.

Contents

Foreword

▶ In April this year our new strategy, *Raising standards, putting people first*, set out a clear purpose for CQC – to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and to encourage care services to improve.

▶ To deliver our purpose, we are making significant changes to how we work. Most importantly, we are acting on the recommendations of the report into the abuse of people with learning disabilities at Winterbourne View, of Robert Francis' report into the failings at Mid Staffordshire NHS Foundation Trust and the government's response to those catastrophic failures of care in *Patients First and Foremost*.

▶ We have listened to independent reviews such as Professor Kieran Walshe's evaluation of our work, Deloitte's report on how we carry out investigations and Grant Thornton's review of our regulatory activity at University Hospitals of Morecambe Bay NHS Foundation Trust. The way the health and social care system is organised now makes it even more important that we work better with others.

▶ This consultation is an important next step towards making the changes needed to deliver our purpose. It sets out the principles underlying how CQC will inspect all services and some more detailed proposals for how we will inspect NHS trusts and foundation trusts and independent acute hospitals. It also includes some joint proposals between CQC and the Department of Health on changes to regulations that underpin our work, including some important new responsibilities for CQC set out in the Care Bill. This is the beginning of a series of consultations on detailed changes to how different types of services will be inspected, with changes being implemented at different times during the next three years.

▶ We approach this work with humility, recognising that the main responsibility for delivering quality care lies with care professionals, clinical staff, providers, and those who arrange and fund local services. However, we are clear that we will expose services providing mediocre and inadequate care and we will have zero tolerance for services where people are failed on the most fundamental aspects of care. At the other end of the spectrum we will acknowledge and highlight the many hospitals, care homes and other services in England where people are receiving good or outstanding care.

▶ The intention is to develop CQC into a strong, independent, expert inspectorate whose evidence-based, professional judgements are welcomed and instructive. How Ofsted approach their work is valued and we will learn from that. We will expect services to be open and honest about any problems they have. If there is a willingness to take responsibility for putting them right, we will take this into account in our response.

▶ Above all, we will always be on the side of people who use services, making sure that they are treated with respect and that their views and experiences of care are listened to and acted on. We will be independent of, but not distant from, our partners in the health and social care system. We will work closely with Healthwatch England to ensure we develop our new approach with people who use services.

▶ We will inspect and regulate different services in different ways based on what has the most impact on the quality of people's care. However, there are some principles that will guide our work:

- When we inspect we will ask the following questions about care services:
  - Are they safe?
  - Are they effective?
  - Are they caring?
  - Are they responsive to people's needs?
  - Are they well-led?
- We will agree clear standards of care that help us judge the quality and safety of services. They will include, but are not limited to, the

fundamentals of care recommended by Robert Francis below which no provider must fall without facing serious consequences. We will work with the National Institute for Health and Care Excellence (NICE) to ensure these align with their quality standards and so provide a comprehensive spectrum of standards, as recommended by Robert Francis.

- We will use **surveillance of information and evidence** to decide when, where and what to inspect, including listening better to people's experiences of care and using the best intelligence from across the system.
- Our inspectors will no longer be generalists who inspect all types of care services. We are now appointing powerful and respected **Chief Inspectors of Hospitals, Social Care and General Practice** to lead national teams of **expert inspectors**. The teams will include **clinical and other experts,** including **people with experience of receiving care**. We will spend longer inspecting NHS hospitals, including in the evenings and weekends when we know people can experience poorer care.
- Our expert inspectors will no longer make statements simply about compliance with standards. They will use professional **judgement,** supported by objective measures and clinical evidence, to assess the quality of services against our five key questions. This will include a **rating** to help people compare services and to highlight where care is good or outstanding and expose where care is inadequate or requires improvement.
- Our Chief Inspectors will use the expert judgements of their teams of inspectors, together with information and evidence held by CQC and our partners in the system, to provide **a single, authoritative assessment of the quality and safety of care services**.
- We will make sure that directors or leaders of organisations make a legal commitment to provide safe, high-quality care and are **personally held to account for it**.
- In NHS hospitals, we will introduce a **clear programme for hospitals** that are failing to provide quality care that makes sure that immediate action is taken to protect people and to hold those responsible to account.

▶ Some of the changes will take up to three years to make. We are grateful for the support of our partners and colleagues across the system in recognising our need to prioritise these, so that the changes to the way we inspect NHS and independent acute hospitals will be introduced first. We welcome the continued support as we begin our dialogue with colleagues in the other sectors. We will hold formal consultations with these sectors, starting with adult social care in autumn 2013.

▶ We will take account of the emerging thinking from other reviews and initiatives, including Don Berwick's task force looking at safety in the NHS, Camilla Cavendish's investigation into the non-professional care workforce in health and social care, and the review of complaints by Professor Tricia Hart and Ann Clwyd MP.

▶ Following the government's response to the failings at Winterbourne View, we are also making some immediate changes for those services caring for people with learning disabilities. We know that there are continuing problems with the quality of care for people with learning disabilities, including lengthy stays in hospital for people away from their families and communities. We will also work with experts in the field to develop a way of inspecting those services that includes looking at whether the right services are being commissioned.

▶ Over the past year we have developed these changes in conversation with the public, our staff, providers, organisations with an interest in our work, clinical and other experts and our partners in the health and social care system. This consultation is a continuation of those valuable discussions. We hope as many people as possible will give us their views and comments. We want to make sure these changes are the right ones and that they help us to deliver our purpose – to make sure health and social care services provide people with safe, effective, compassionate, high-quality care.

David Prior
Chair

David Behan
Chief Executive

Section 1: Introduction

This document asks what you think of our proposals to make significant changes to the way we inspect and regulate health and social care. It is the first of a series of consultations we will hold between now and 2016 as we develop and introduce different changes for different types of services.

We are committed to developing them in partnership with the public, people who use services, our staff, our partners in the system, experts, providers, and organisations with an interest in our work and we have an extensive programme of engagement planned to do this.

▶ Our proposed timescales for introducing the changes are set out below.

▶ **Section 2** of this document sets out the principles for our inspection and regulation of all care services. **It applies to everyone we regulate.** It includes:

- A better registration system for those applying to offer new care services, including holding senior managers, boards and directors of services to account for poor-quality care.
- Intelligent monitoring of information and evidence to decide when, where and what to inspect, including listening better to people's experiences of care.
- Improvements to how we will inspect services, including the introduction of Chief Inspectors to lead expert teams.
- Clear standards of care including, but not limited to, the fundamentals of care below which no provider must fall.
- A ratings system to help people choose between services and to encourage improvement.
- The action we will take in response to poor care.

▶ **Section 3** sets out more details on a new way of **inspecting and regulating NHS and independent acute hospitals**, including:

- The indicators that we will use to trigger action in our monitoring of information and evidence about acute hospitals.
- Longer, more thorough hospital inspections where required.
- A clear programme for failing hospitals that makes sure immediate action is taken to protect people and to hold those responsible to account.
- How we will issue and review ratings for acute hospitals.

▶ **Section 4** sets out proposals for changes to regulations made by the Department of Health and CQC which underpin our current proposals. This section of the consultation **applies to all providers registered with us**.

▶ **Section 5** repeats the consultation questions that we are asking throughout this document.

Finally, this document is accompanied by:

- A draft **Equality and Human Rights Duties Impact Analysis** – which gives more detail about the impact of the proposed changes on equality and human rights and how they will promote equality and human rights for people who use health and social care services.
- A draft **Regulatory Impact Assessment** – which outlines the costs and benefits to providers and people who use services.

Both of these impact assessments will be updated and published as final versions when we publish our response to this consultation.

When we will introduce the changes

▶ In **June 2013** the Department of Health will consult on plans to strengthen corporate accountability in the wake of events at Winterbourne View hospital.

▶ From **July 2013** we will build on the commitments we made in the government's response to the failures at Winterbourne View and make sure that named directors, managers and leaders of services for people with learning disabilities commit to meeting our standards and are held to account for it.

▶ From **October 2013**, we will begin to change the way we inspect NHS and independent acute hospitals, because we recognise there is an urgent need to improve how we do this. The new Chief Inspector will spearhead a more specialist, expert and risk-based approach to inspection.

▶ We will award a rating for a hospital once we have inspected it under the new approach. As we do not yet have the legal powers to award ratings, our initial ratings will be in shadow form, and they will be confirmed subject to the passage of legislation through Parliament.

▶ We will also begin to develop changes to the way we inspect other services, prioritising those where people are in the most vulnerable circumstances and where there are higher risks to people.

- In **2014/15** we will introduce changes to the way we inspect all services for people with learning disabilities and mental health issues provided by NHS trusts and independent healthcare providers.
- Also in **2014/15** we will begin to change the way we inspect adult social care services, including introducing ratings. We will run the first of our consultations for adult social care in **autumn 2013** which will set out our initial thinking on how we will change our regulatory approach for this sector.

▶ Over the next two years we will review and develop changes to the way we inspect other services, including those who provide GP, out-of-hours and dental services. Our Chief Inspector of General Practice will lead this work, including the development of ratings for providers of GP services. This year we will run the first of our consultations for general practice which will set out our initial thinking on our new regulatory approach. We have not yet decided whether we will rate services such as dental practices and those that provide cosmetic surgery.

▶ **In 2015/16** we will make changes to our inspection of community healthcare and ambulance trusts, including introducing ratings.

At a glance:
What's changing in the way we regulate and inspect

From	To
• Focus on Yes/No 'compliance' • A low and unclear bar	• Professional, intelligence-based judgements • Ratings – clear reports that talk about safe, effective, caring, responsive and well-led care
• 28 regulations, 16 outcomes	• Five key questions
• CQC as part of the system with responsibility for improvement	• On the side of people who use services • Providers and commissioners clearly responsible for improvement
• Generalist inspectors	• Specialists, with teams of experts • Longer, thorough and people-focused inspections
• Corporate body and registered manager held to account for the quality of care	• Individuals at Board level also held to account for the quality of care

Section 2: An overview of how we will inspect and regulate all care services

We will inspect and regulate different services in different ways based on what has the most impact on the quality of people's care.

However, there are some general principles that will guide our future 'operating model'. They apply to: the way we register those that apply to CQC to provide care services; the standards that those services have to meet; how we use data, evidence and information to monitor services; the expert inspections we carry out; the information we provide to the public on our judgements about care quality, including a rating to help people compare services; the action we take to require improvements and, where necessary, the action we take to make sure those responsible for poor care are held accountable for it.

FIGURE 1: OVERVIEW OF OUR FUTURE OPERATING MODEL

Asking the right questions about the quality and safety of care

To get to the heart of people's experience of care, we need to make sure we ask the right questions about the quality of services, based on the things that matter to people. We will ask the following five questions of every service:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

We developed these five questions with reference to the areas that Lord Darzi defined as central to quality in healthcare: safety, clinical effectiveness and the experience of people who use services. The first two of these link directly to our key questions: whether a service is safe and effective. However, because we regulate social care as well as health services, our approach to assessing effectiveness will be broader than clinical effectiveness.

We have separated the experience of people who use services into two parts: how caring a service is and how responsive it is to meeting people's needs. And although leadership, governance and culture has not been a formal element of our existing approach, our experience has shown that these factors make the difference between success and failure.

We will develop guidance on what we will focus on when we carry out an inspection to provide a judgement in relation to all of the five key areas, working with our strategic partners and drawing on developments and emerging thinking from the field. We will consult publicly on the guidance we develop, including how we will focus the new approach to providing a judgement on the five questions for different sectors to make sure it is relevant and tailored appropriately.

What do we mean by these five questions?

▶ By **safe**, we mean that people are protected from physical, psychological or emotional harm. For example, are people getting MRSA (a hospital-acquired infection) because of poor hygiene?

Unacceptable care example

We found repeated safety issues at one care home. Our inspectors saw members of staff lifting people from their wheelchairs by holding them under their arms. This is not safe practice and increases the risk of injury.

Staff told inspectors they weren't sure about some residents' medical conditions because they were given no instructions, support or guidance. And there was no system in place to make sure people got the fluids they needed to keep them hydrated. Records for fluid intake were inconsistent and incomplete. One member of staff had been administering medication without any training, putting people using the service at great risk.

Some staff files contained no application forms, references or updated disclosure and barring checks, and there was no evidence that staff had completed health questionnaires to show they were fit and suitable to work at the home.

There were not enough qualified, skilled and experienced staff to meet people's needs. Staffing levels needed to reflect the dependency levels of people and be reviewed on a daily basis.

In our approach to safety, we have been consulting Don Berwick's task force on achieving zero harm and talking to the Health Foundation about their research into measuring and monitoring safety, with a view to working with them to develop our approach to measuring and monitoring safety, leadership and culture.

▶ By **effective** we mean that people's needs are met, and their care is in line with nationally-recognised guidelines and relevant NICE quality standards or that effective new techniques are used which give them the best chance of getting better or living independently. For example is there an effective 'enhanced recovery' programme following surgery?

Unacceptable care example

A number of women with breast cancer were recalled by an NHS trust due to issues surrounding their test results. We found that their processes to assess and assure themselves of the quality of service had not been effective or robust enough.

There had been poor communication between pathologists, the clinical governance committee and the board of directors. The pathology department had been without a leader for five years, with the role being covered by locum staff, and a number of permanent posts were not filled. Equipment used by the department was outdated. Decision making in the clinical governance committee was not always clear. The hospital's action plan in relation to mortality rates was not being clearly monitored by the board and had not been subject to in-depth analysis.

On effectiveness, we will be informed by the work of NICE, the Social Care Institute for Excellence (SCIE) and professional organisations with an active interest in this area.

▶ By **caring**, we mean that people are treated with compassion, respect and dignity and that care is tailored to their needs. For example, do care home staff understand people's individual needs, spend time talking to them and make sure they have the opportunity to take part in activities that they enjoy?

Unacceptable care example

At one care home, we saw that there was very little stimulation for people using the service. Staff did not interact positively with people or engage with them in any meaningful way. One member of staff came into the lounge shortly after starting her shift, walked straight past the 12 people sitting in the room without speaking or acknowledging any of them, and sat down at a table. After 10 minutes had gone by, we asked her if she had spoken to any of the people using the service since she began her shift. She said she had not. Staff spoke more to one another than they did with people using the service.

Our approach to monitoring how caring a service is will be informed by Compassion in Practice – the new three-year vision and strategy for nursing, midwifery and care staff led by Jane Cummings, the Chief Nursing Officer for England and Viv Bennett, Director of Nursing at the Department of Health.

▶ By **responsive**, we mean that people get the treatment and care at the right time, without excessive delay, and that they are listened to in a way that responds to their needs and concerns. For example, is a GP surgery open at times to suit the needs of the local population?

Unacceptable care example

We arrived at a care home at 5.30am because concerns had been raised with us about the times people were woken by staff. We found that some residents were already awake and dressed. Staff members had also started to attend to some people's personal hygiene needs. They told us they had been instructed to do this by senior staff.

It was clear that some people were not always involved in making decisions about their own care. Their care plans did not record what time they preferred to, or usually woke up, what time they liked to go to bed or when they needed help with hygiene.

Some of the care plans had a brief statement about the person's independence, but not enough information to help staff support people to remain as independent as possible. When one resident went to make their own cup of tea, a member of staff told them not to as it was their job.

We will also work closely with bodies that speak on behalf of people who use services, such as the Healthwatch network, to develop our approach to assessing responsiveness and to ensure that the focus of our assessment across the five key questions is firmly rooted in the experiences and views of people who use services.

▶ By **well-led**, we mean that there is effective leadership, governance (clinical and corporate) and clinical involvement at all levels of the organisation, and an open, fair and transparent culture that listens and learns from people's views and experiences to make improvements. The focus of this is on quality. For example, does a hospital board make decisions about quality care based on sound evidence and information about their services, and are concerns discussed in an open and frank way? Is there a good complaints procedure that drives improvement?

Unacceptable care example

Inspections at an NHS trust found issues of poor management, in particular failing to properly train and supervise staff across three hospitals.

A number of staff had not received clinical supervision or the appropriate professional development support that would enable them to be suitably skilled and confident to carry out their role. Trust-wide records showed significant gaps in mandatory staff training, including moving and handling, safeguarding of adults and children, resuscitation and infection control.

At two of the hospitals there were other problems. In one, patients were not always being admitted to the right ward because of a shortage of beds. Patients with a range of conditions were being treated on the stroke ward, with a significant impact on those people who needed specialist stroke care.

In the other, patient records contained inconsistent information, and in some cases there was a lack of evidence to show that care and treatment was being appropriately planned and delivered.

Well-led will encompass an assessment of aspects of governance, leadership and culture as part of our inspections. Our initial focus will be on effective governance, drawing on our current standards of assessing and monitoring the quality of service provision. In assessing whether NHS services are well-led, we will be working with Monitor, the NHS Trust Development Authority (NHS TDA) and NHS England to ensure that our approaches are both consistent and complementary. The NHS TDA and Monitor will continue to lead on all aspects of financial sustainability and corporate governance. We will develop our approach to quality governance, assessing leadership and culture on a slightly longer timeframe, based on evidence of what is most important at organisation, service, team and individual levels and in collaboration with experts in the field.

How do the five questions fit with the Outcome Frameworks?

The government has published Outcome Frameworks for the NHS, for adult social care and for public health. These set out the measures against which the health and care of the population will be judged. Our five questions are complementary to the Outcome Frameworks, as they look at the care provided by an individual provider, rather than the overall heath and care status of a population (which will be dependent on many different providers, as well as other factors).

A better system for organisations applying to provide care services

The terrible abuse that was allowed to happen at Winterbourne View hospital showed that providers need to be fully accountable for making sure they can deliver personalised, local and high-quality services for people. The system and checks we use when providers apply to register with us need to be stronger, to make sure that those who intend to provide care are focused on high-quality care and understand the commitment they are making to people about the care they will receive.

▶ We will introduce a better system for providers applying to register with us to provide care. We will do this by making sure that:

- The process of registering with CQC is effective and efficient, partly through building efficient digital services that will transform the way all providers get involved and communicate with us.
- Providers who already deliver good quality care can offer new services easily.
- There is a more robust test for providers whose ability to deliver quality care is less clear.
- Those we register make a commitment to deliver safe, effective, compassionate, high-quality care.
- Named directors or leaders of organisations are personally held to account for that commitment. This is in addition to making sure providers and registered managers are held to account for the care they provide.
- Those we register show us that they have good plans for how they will provide care, including an effective system for spotting and dealing with problems. They must also show us that they focus on the right things when they employ staff, such as their qualifications, clinical supervision and continuing professional development, and that they are committed to listening and acting on the views and experiences of people who use their service.

▶ From July 2013 we will start to apply this different system to those offering services for people with learning disabilities. We will learn from this when we adapt and extend it to other types of services in the future.

▶ We will work towards making sure that when those who provide care services register a change of name or a new owner, they cannot do this in a way that hides any previous or current concerns about the quality and safety of the service from CQC or from the public.

▶ The Department of Health is proposing to make changes to regulations that support these improvements and which would make it easier for CQC to take tough action, including prosecution.

Why we are focusing on people with learning disabilities

Winterbourne View exposed an appalling story of abuse. CQC undertook a series of inspections of similar facilities and found further examples of people being "assessed" for periods of many years with a model of care that was frankly wrong.

Many of these services are located in the independent healthcare sector, and we know from our 'State of Care' reports that this is an area where far too many providers fail to meet our standards.

The CQC is a signatory to the Concordat that has come out of Winterbourne View. As part of the government's commitment to bring about change, the Care Services Minister, Norman Lamb, has made it clear that this model of care should no longer be commissioned.

In registering learning disability services, we will focus on the following:

- Being more rigorous at the point of registration. All new services will need to outline their model of care, show how they will deal with concerns about quality, and say who is responsible at various levels of the organisation for quality.
- We will not simply look at new registrants. We will also apply the same processes and assessments to existing providers.
- We will develop the knowledge and skills of our current inspectors and registration staff so that they have a good understanding of what an appropriate model of care looks like.
- Although the provision of care and its quality is the absolute responsibility of the provider, we recognise that commissioning is vital in this specialist area. We will routinely discuss our inspections with those commissioning packages of care.
- We are working with the Joint Improvement team funded by the Department of Health and the Local Government Association – with the aim of supporting commissioner assessments of all people with learning disabilities currently in the system.

Intelligent monitoring of information and evidence about the quality and safety of care

We do not always make the best use of all the information available to us in terms of directing our regulatory activity. We will rethink and redesign the way we use information. In the future, we will be clearer about the indicators that are most important in monitoring the quality of care and focus on the information that matters for each type of care.

▶ We will make better decisions about when, where and what to inspect by using information and evidence in a more focused and open way. We will monitor this information continuously to anticipate, identify and respond more quickly to services that are at risk of failing with respect to the quality of care they provide.

▶ We will continue to gather information from national and local data and intelligence sources, past inspections, and from local authority overview and scrutiny committees. We will also make sure we understand the reality of people's individual experiences of care, including working closely with local Healthwatch and local voluntary groups. Information from people who use care services about the quality and safety of their care, including concerns and complaints, will be a vital source of information. The outcome of the Clwyd/Hart review of NHS complaints will help us to shape our approach. We will take full account of information from care staff, including 'whistleblowers'. We will continue to listen and act on the concerns of whistleblowers through our dedicated whistleblowers' helpline.

▶ You can read more about our extensive proposals for making better use of information and evidence in our intelligent monitoring of NHS hospitals in section 3. We will consider how these proposals can best be applied to other sectors. We know that the availability of national data varies – we will take this into account as we design how we make best use of intelligence. We will consult

on each proposed set of indicators as they are developed and continue to develop our approach as more information becomes available.

Simple, clear standards to help us judge the quality and safety of services

In the past, our approach has been to concentrate on a legal statement about whether or not a provider is complying with standards of quality and safety. In future we will go beyond statements of legal compliance, and tell people in clear and simple language what we think about the quality and safety of the care given by that provider.

▶ We will make sure the public are clear about the safety and quality of care they can expect from their health and social care services. We will simplify our approach to reflect the five questions we will ask about the quality and safety of services.

▶ These standards will help us to judge whether or not services are safe, effective, caring, responsive to people's needs and well-led when we are registering, inspecting and rating services. However, we will use them to support our professional judgements about these five key areas rather than to record 'compliance' or 'non-compliance' with standards.

▶ We have reflected on the findings and suggestions made by Robert Francis in terms of having clear and simple standards against which care can be judged. He talked in his report about the use of 'Fundamental Standards' and how these would sit within a broader set of enhanced and developmental standards. We have looked at these suggestions and we propose that we would build on his proposals to look at:

- Fundamentals of care
- Expected standards
- High-quality care.

▶ To be successful, these levels must be owned by those charged with delivering the very highest standards of care to people. We will therefore be actively engaging with clinical professionals and representative bodies to ensure the standards are meaningful to those delivering front-line care, alongside our engagement with people who use services.

▶ All care services will be required by law to meet the fundamentals of care and the expected standards. We will make sure that the bar for each of these levels is very clear.

▶ The fundamentals of care represent the basic requirements that should be the core of any service. They should help to set the context for delivering compassionate, safe care.

Fundamentals of care

▶ In its response to the Francis Inquiry, *Patients First and Foremost*[1], the government committed to draw up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with CQC. The government is also committed to a full consultation on these new standards, and we have a number of questions on which we need people's views.

▶ The fundamentals of care will set a clear bar below which standards of care should not fall. These will focus on the very basics of care that matter to people and will be easily understood by all. There will be immediate, serious consequences for services where care falls below these levels, including possible prosecution. Anyone should be able to recognise a breach of the fundamentals of care, even in the absence of specific guidance.

▶ We want to start a genuine public discussion of what these fundamentals of care should be. The examples below are purely to stimulate this debate:

- I will be cared for in a clean environment.
- I will be protected from abuse and discrimination.

1. www.gov.uk/government/publications/government-initial-response-to-the-mid-staffs-report

- I will be protected from harm[2] during my care and treatment.
- I will be given pain relief or other prescribed medication when I need it.
- When I am discharged my ongoing care will have been organised properly first.
- I will be helped to use the toilet and to wash when I need it.
- I will be given enough food and drink and helped to eat and drink if I need it.
- If I complain about my care, I will be listened to and not victimised as a result.
- I will not be held against my will, coerced or denied care and treatment without my consent or the proper legal authority.

It is our intention that the new regulations will allow CQC to prosecute breaches of fundamentals of care without the need to issue a warning notice first.

We know that not all of the fundamentals of care will feel equally relevant to all sectors and would welcome your views on this.

Expected standards

Expected standards set out what anyone using a service can expect as a matter of course. They set a higher bar than the fundamentals of care and will relate directly to whether a service is:

- Safe
- Effective
- Caring
- Responsive
- Well-led

We will look at whether any of our existing 'essential standards' could be reflected in the new expected standards. For example:

▶ There will always be enough members of staff available to keep me safe and meet my health and welfare needs.

▶ My personal records will be accurate and kept safe and confidential.

Where services do not meet them, we will require improvements to be made, using our legal powers as necessary. **Section 4** describes how these expected standards, alongside the fundamentals of care, will be given legal force through a small number of registration requirements. We will be using this opportunity to have as few regulations as possible, to reduce bureaucracy and meet the government's 'Red Tape Challenge'.

Minimising bureaucracy and administrative costs

CQC is a core member of the NHS Confederation's initiative which aims to reduce bureaucracy in the NHS by at least a third. Our new approach to inspection is designed with this objective firmly in mind.

- We will work with the Department of Health to radically streamline and reduce the regulations which set out fundamental and expected standards of care, and the guidance that we issue to support them.
- By approaching inspection from the perspective of peer review – clinical staff engaging with clinical staff – we will make it feel much less like 'being done to'.
- We will coordinate with existing visits and inspections, such as Royal College visits, to minimise duplication and overlap, for example through joint visits and re-use of each other's findings.
- Our approach to information only uses existing information, and does so in a more targeted, intelligent way than before.
- We will continue to respond to the healthy living and social care strand of the Red Tape Challenge and work with the Focus on Enforcement team within the Better Regulation Executive.

2. We recognise that certain interventions and treatments can involve a degree of harm that is inevitable and that errors may occur. However, we would expect a provider to take appropriate steps to minimise the risk of harm. A provider would breach the fundamentals of care if they did not follow nationally recognised procedures and practices to prevent or avoid harm, or they tolerated harm in a way that is unreasonable – for example through unchecked reckless practice or neglect.

- We are working closely with Monitor, the NHS TDA and NHS England to review information flows, foundation trust authorisation process and fit and proper person tests, to align these where appropriate. We are developing approaches to assessing culture, leadership and governance which aim to be common as far as possible and consistent in all regards.
- We are an 'early adopter' for a new approach to impact assessment which the Better Regulation Executive is promoting. Our regulatory impact assessment alongside this consultation does not just set out our estimates and invite challenge. Instead, it identifies the areas where impacts will change and invites provider representative bodies to advise us on how great those impacts are likely to be. We will engage with those bodies and take their assessment of impacts into account in our final proposals.

Following this consultation, the Department of Health will issue a draft of the new regulations for further discussion in the autumn, and CQC will issue draft guidance on the expected standards in parallel. The guidance will contain some examples of what is, and is not, acceptable while making it clear that providers will not be able to 'tick boxes' and expect good ratings.

The guidance will replace the existing, detailed *Guidance about compliance* and will recognise the different care experiences possible, ranging from treatment in a hospital to visiting a GP or living in residential care. It will make it clear that a person's wellbeing must be considered, particularly where people are generally cared for longer term, at home, in hospital or in residential care.

Example: Judging whether a maternity service is meeting expected standards

This example is for illustrative purposes only.

Is care safe?

- The provider learns from any safety incidents that have occurred and changes practices in response.
- Staffing levels and skill mix are set using recognised tools, for example those recognised by the Royal College of Midwives and Royal College of Obstetrics and Gynaecology guidelines.

Is care effective?

- Care is delivered at the right time and by staff with the right qualifications and training. For example, do all women have a dedicated midwife who stays with them throughout established labour and birth?
- Care is delivered in line with recognised, evidence-based guidelines (for example, NICE and Royal College guidelines) and achieves the expected outcomes for mothers and babies.
- Care is delivered in a planned way in accordance with assessed needs, and the experiences of women, their partners and families are monitored.

Is it caring?

- Women, their partners and families report that staff are caring, and staff are observed to be caring.

Is care responsive?

- Care is delivered in response to the population that the provider serves, as well as individuals' changing needs.

Is care well-led?

- The maternity services have clear clinical leadership and all staff work in partnership.
- The provider manages the risks related to the delivery of a maternity service effectively. It understands where its risks are at service level through to Board level and the Board supports changes to be made to minimise risk and provide a good service.

High-quality care

The definition of high-quality care will be led by organisations such as NICE. For example, NICE quality standards, which are a concise set of statements designed to drive and measure priority quality improvements within a particular area of care, set out what high-quality care looks like. Our inspectors will use good practice guidance developed by these other organisations to identify and describe whether a service is providing high-quality care. We will also look for where providers are using new ways of providing good, innovative care.

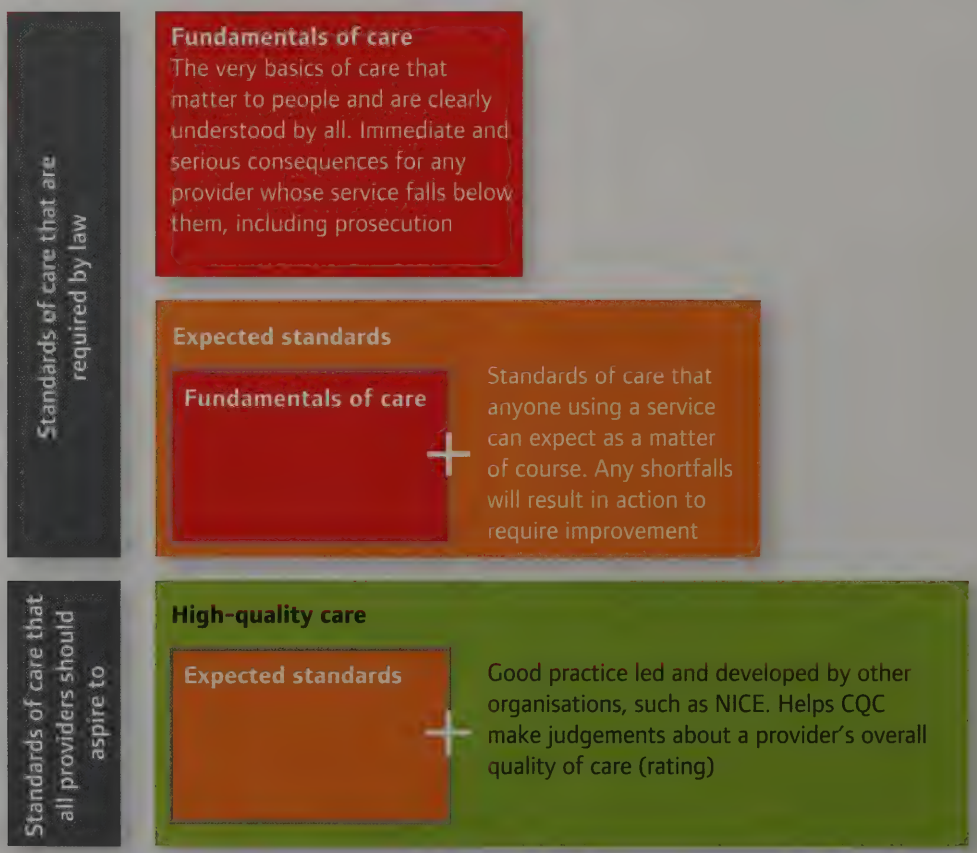
Ensuring that regulation encourages innovation in good practice

Regulation should not discourage innovation, but provide a framework to assure that the risk of untried approaches is safe. We will do this by developing expert, knowledgeable judgement and by avoiding 'black or white' interpretation of standards.

As well as using experts in our inspection teams, we will also use expert advisors when we consider applications for new services. Our registration process will place more emphasis on providers declaring how they will assure safety and who will be responsible for that. We will check that is credible, and then hold the provider to account for it through our inspections, but we will not dictate how they do so.

When we inspect, our reports will not focus only on concerns. They will highlight where there is innovative practice that others could learn from. The ratings that we issue will also recognise it: we will expect any provider who achieves an 'outstanding' rating to demonstrate innovative practice.

FIGURE 2: FUNDAMENTALS OF CARE, EXPECTED STANDARDS, AND HIGH-QUALITY CARE



Expert inspection teams, led by Chief Inspectors of Hospitals, Social Care and General Practice

▶ We are appointing powerful Chief Inspectors of Hospitals, Social Care and General Practice to lead national teams of inspectors who specialise in particular types of care. The Chief Inspector of Hospitals was a central recommendation of *Patients First and Foremost*. One of the country's leading clinicians, Professor Sir Mike Richards, will be our Chief Inspector of Hospitals, bringing his extensive experience and knowledge of clinical delivery to our inspections of hospitals.

▶ Our Chief Inspectors will shine a powerful light on the quality and safety of care, working closely together to improve people's care as they move between different parts of the health and social care system. Their teams will include independent clinical and other experts, such as people with in-depth experience of using care services. Our inspectors will use data and evidence, including information from the public and people who work in a service, and from our partners in the system, to help them decide where, when and what to inspect.

▶ On our inspections we will speak to more people who use services and frontline staff to hear about the reality of the care they receive, to senior managers and to board members. We will also inspect at nights and at weekends services that provide 24-hour care, as we know there is often less supervision at these times and people can experience poorer care.

▶ Our inspectors will use professional judgement, supported by objective measures, to assess the quality and safety of care. They will also issue a rating which will highlight good and outstanding care, expose mediocre and inadequate care and encourage services to improve.

▶ We will improve the links between our work under the Mental Health Act and how we regulate mental health services to protect the human rights of people who are in vulnerable circumstances, particularly those who, because of concerns about their safety and the safety of others, have had their freedom restricted by being detained and treated against their will. This will mean greater alignment of Mental Health Act activity and inspection visits and more involvement of Experts by Experience in Mental Health Act monitoring.

▶ We are also committed to strengthening the protection of people with learning disabilities, whether or not they are detained. We will give particular attention to making sure we hear the views of people on mental health wards.

▶ We also wish to strengthen the understanding of the Mental Capacity Act by providers, inspectors and commissioners. This Act underpins the care of two million people in health and social care settings and we want to ensure that its principles are promoted and people with mental capacity issues receive care of the same standard as anyone else.

▶ We work closely with other inspectorates, in particular Ofsted in respect of children's health and care services and HMI Prisons, HMI Probation and HMI Constabulary in respect of people in prisons, young offender institutions and police custody. This is important work that helps all partners shape their understanding of the care being provided.

▶ How often we inspect, how long we spend on an inspection, and the size and membership of the inspection team will be based on the 'risk' of the service – the type of care being offered, the vulnerability of the circumstances of people who use it, the information we have about a service, and its current rating. We will inspect services less often if we are confident that they are offering safe, high-quality care and can continue to do so. We will focus less on the number of inspections we carry out and more on the number of days we spend inspecting services.

The action we will take

▶ We will expect and encourage those who provide care to be open and honest about issues and problems that are affecting the quality and safety of people's care. We expect them to respond positively to feedback and to take action to put things right where necessary. We are clear that it is the responsibility of those who run and work in the service to improve it.

▶ We will follow up on all of our inspections and judgements to make sure that a service has improved or remains high-quality care. Our Chief Inspector of Hospitals will play a key role in working with local partners such as Quality Surveillance Groups and through risk summits to help decide the action we will take where care is below the standards.

▶ We have a range of existing powers we can use to make sure the service takes action. For example, we can issue a formal warning requiring improvements within a certain timescale and if necessary, we can suspend a service or cancel its registration.

▶ In the future, our powers in relation to NHS trusts and NHS foundation trusts (acute, mental health, community health and ambulance trusts) will change as we work more closely with Monitor and the NHS TDA. You can read more about this in section 3 of this document.

▶ In other services, we will have new powers from April 2014 to:

- Hold Board members to account for failing to honour their commitments to provide safe, high-quality care. This could result in them being removed from their posts.
- Prosecute a provider for failing to provide fundamental levels of care, without having to issue a formal warning first (this is reliant on legislation being passed by Parliament).
- Make sure the service is open and honest with the people who use the service and their families about things that have gone wrong and why they happened – this will be covered by the new 'duty of candour' planned for inclusion in revised CQC regulations.

▶ The Department of Health will shortly consult on the accountabilities of board members in parallel to this consultation, which are planned for inclusion in the revised CQC regulations.

▶ We will make sure that our partners in the system take action. This could include asking a professional regulator such as the General Medical Council or the Nursing and Midwifery Council to act, or referring the failure to the Health and Safety Executive which could lead to investigation and prosecution. We set out more information on the action we will take in section 3 of this document.

Better information for the public

▶ Our inspection reports will explain the reason for the inspection and describe our findings, assessment and judgments on whether a service is:

- Safe
- Effective
- Caring
- Responsive to people's needs
- Well-led.

▶ They will include a simple summary of the main points for each of the five questions so that people can quickly understand the quality and safety of the service, together with more detail. They will set out clear areas of excellence and areas where improvement is required and explain what will happen next. As the next section discusses, this will also include a rating to help people compare services.

How we will involve people who use services in developing the new fundamentals of care, expected standards and the information the public need

- The views of the public are vital. We plan to engage widely with people who use services and the public, representative groups and national and local charities about the detail of this consultation.
- We will work closely with Healthwatch England and hold workshops with them to get their views and ideas and channel public feedback.
- We will hold small focus groups to explore public understanding of the proposed changes, what they think constitute the fundamentals of care, and what information is of most value at the point of choosing care.
- We will be hosting a number of events for the public and representative groups across the country to give us their feedback face-to-face, and also a one-day detailed engagement workshop with up to 20 members of the public.
- We will host online discussions with our Public Reference Group and our 'people who use services' advisory group, and a range of surveys and exercises on our website, to explore the expectations of the public about what standards of care are meaningful to them and where they would expect to find the information they need.
- We will also meet with a number of community groups via CQC's SpeakOut network.

Ratings to make clear the quality of care and to help people choose between services

▶ Over the next three years we will develop a ratings system for most providers of health and social care. Our ratings will develop to become the single, authoritative assessment of the quality and safety provided by an organisation. They will be primarily based on the judgements of our inspectors about whether services are safe, effective, caring, responsive to people's needs and well-led, and will take into account all the information we hold about a service and the findings of others. We will develop them in partnership with the public, partner organisations, providers of services, clinical and other experts. This will build on the work carried out by the Nuffield Trust in *Rating Providers for Quality: a policy worth pursuing?* (March 2013). This report set out advice on a rating system for GP practices, hospitals, care homes and providers of home care.

▶ We may also use the accreditation schemes or findings of any clinical audit or inspections by other organisations such as the Royal Colleges (for example, of Surgeons, Physicians, Psychiatrists, etc) to contribute to ratings. We will actively develop this approach with the Royal Colleges.

▶ We will also be keen to draw on the insight and day-to-day understanding of partners such as local authorities, health and wellbeing boards, overview and scrutiny committees, and of commissioners such as clinical commissioning groups and GPs in their interaction with the services they commission.

▶ Ratings will be updated as a result of inspections by our expert teams. In healthcare, this is a fundamental change from the annual rating system of the previous regulator. How often inspections take place will depend on the last rating and our continuous monitoring of services.

▶ We will publish the information on which the rating is based.

▶ We will make clear on our website when a service is being inspected so that the public understands that our judgement and rating might change. We will publish any new rating as quickly as possible following our inspections. Our aim will be to make sure the public has access to timely, independent, clear, accurate information about the quality and safety of their local services.

▶ Our Chief Inspectors will use the expert findings, ratings and judgements of their teams of inspectors, together with information and evidence held by CQC and our partners in the system, to enable CQC to provide a single, authoritative assessment of the quality and safety of care of the services we regulate.

▶ We will begin by rating providers of acute services from December 2013, with an aim that all these providers receive a rating before the end of 2015. We will begin to introduce ratings for mental health trusts during 2014 and begin to introduce ratings for all other NHS trusts, for example community healthcare and ambulance trusts, during 2015 /16.

▶ We will also start to introduce ratings for adult social care services from 2014/15 and for most other remaining services from 2015/16. We have not yet decided whether we will rate services such as dentists and those that provide cosmetic surgery.

▶ You can read more detail about our proposals for rating acute hospitals in section 3.

Investigations and reviews of particular aspects of care

▶ In the past, we have tended to use our investigation powers in relation to an individual provider. In future we intend to use our investigation powers to take a more strategic look at care pathways and how people are cared for when they move between services. For example, we could investigate the care of older people with complex health issues who need to use more than one service. We will explore options for carrying these out in partnership with other organisations.

▶ Investigations will also be used to identify the causes of actual or potential systemic failures in quality and safety in a local area or region – for example, the pressure on maternity services in a particular area.

▶ We are developing a better system of deciding which particular aspects of health and social care we should focus on. Our inspections and reviews of particular aspects of care may, for example focus on people's access to mental health services during emergencies, and whether swift, effective assessments are available which include looking at alternatives to admission to hospital.

▶ We will also look at how well particular care services work together within a region for people, for example early diagnosis, specialist services and long-term care of people with dementia.

Judging the full range of care a person receives: why we want to focus on integration

In establishing the Chief Inspectors of Hospitals, Social Care and Primary Care, we think we will bring a sharp and specialist focus to the quality and safety issues in each of these specific areas. Balanced with this, we will ensure that we do not work in silos.

We know that people do not use services in isolation. We think it is vitally important to look across a range of services and whether or not they work in a coordinated way for the benefit of service users.

For that reason we will strengthen our thematic work.

How we will do this

Our thematic approach enables us to:

1. Take a national overview of health and social care – an example of this might be looking at emergency access to mental health services, and whether swift, effective assessments are available which include looking at alternatives to admission to hospital.

2. Select a set of whole local health and social care systems, looking at how they function together and whether the expected level of integration exists – an example of this might be looking at the range of services that a person with dementia might use in a number of geographical areas, from primary care and early diagnosis, through to specialist services, and what people need in terms of long-term care.

Our inspection powers will allow us to look at whole systems, care pathways and transitions between services, including looking at how services are commissioned and the role of partner organisations.

All three of the new Chief Inspectors will need to contribute to these processes, and this will be part of their role.

Consultation questions

General

1. What do you think about the overall changes we are making to how we regulate? What do you like about them? Do you have any concerns?
2. Do you agree with our definitions of the five questions we will ask about quality and safety (is the service safe, effective, caring, responsive and well-led)?

Fundamentals of care

3. Do you think any of the areas in the draft fundamentals of care above should not be included?
4. Do you think there are additional areas that should be fundamentals of care?
5. Are the fundamentals of care expressed in a way that makes it clear whether a standard has been broken?
6. Do the draft fundamentals of care feel relevant to all groups of people and settings?

Section 3: How we will inspect and regulate NHS and independent acute hospitals

CQC is part of a broader system of regulation and improvement in the NHS. Our role in the system is both to highlight where care is good or outstanding and to expose where care is inadequate or requires improvement.

However, we do not act alone. Providers are responsible for the quality of their services and for driving improvement. Other national bodies, including Monitor and NHS TDA, and commissioning bodies play a key part in making improvement happen. This matters – a judgement by CQC that a local service is failing should not be seen as a 'life sentence'. Services can and should improve, and the NHS system has a duty to support this.

The changes we are making to our approach will ensure that we fulfil our role in this broader regulatory system. The first significant step has been the appointment of a Chief Inspector of Hospitals, who will oversee the development of the new inspection model and the ratings system.

Surveillance of the quality and safety of care in acute hospitals

▶ We will monitor information and evidence to anticipate, identify and respond more quickly to acute hospitals that are failing, or are at risk of failing.

▶ Our approach will be to use indicators to raise questions about the quality of care provided in an acute hospital. The indicators on their own will not be used to draw definitive conclusions or judge the quality of care – that will be a matter for inspection. Instead the indicators will be used as 'smoke detectors', which will start to sound if a hospital is outside the expected range of performance or is showing declining performance over time for one or more indicators. We will then assess what the most appropriate response should be.

Professor Sir Mike Richards will be the new Chief Inspector of Hospitals

The Chief Inspector will be responsible for assessing and judging how well hospitals put the quality of care and the interests of patients at the heart of everything that they do.

He will oversee a national team of expert hospital inspectors that will carry out targeted inspections in response to quality concerns, and regional teams of inspectors who will undertake routine inspections on a regular basis of all hospitals. He will also lead the development of a ratings system for acute hospitals and mental health trusts.

Mike Richards has a track record of supporting patients and entrenching patient safety and compassion at the heart of hospitals, where they belong. He brings with him the confidence of clinical leaders, staff and managers throughout the NHS, which will be crucial to the success of the Chief Inspector of Hospitals role. He will sit on the CQC Board and make key judgements on quality in hospitals.

Mike Richards has transformed cancer treatment in this country and played a big part in changing perceptions about what patients have a right to expect from hospitals. He has shown persistence and success as a leader in his pursuit of needed and challenging change. He has been instrumental in championing peer review and engaging clinicians to drive improvement.

He joins CQC from NHS England, where he was appointed as lead Director with responsibility for reducing premature mortality across all conditions.

In 1999 he was appointed as the first National Cancer Director at the Department of Health, leading the development of the NHS Cancer Plan, the first comprehensive strategy to tackle cancer in England. He also led the development of the End of Life Care Strategy.

Prior to his appointment to the Department of Health, Mike Richards was a Consultant Medical Oncologist at Guy's Hospital specialising in breast cancer (1986 – 1995) and Sainsbury Professor of Palliative Medicine at St Thomas' Hospital (1995 – 1999).

▶ We have identified a small set of indicators by looking at the key quality and safety issues for NHS hospitals and identifying the data available to measure them. We have based them around the five main questions we will ask about services:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive to people's needs?
- Are they well-led?

We recognise, however, that many indicators, complaints for example, will cut across more than one or all of these questions.

▶ There is potentially an unlimited set of indicators that we could monitor in relation to acute hospitals. We have grouped the indicators into three sets according to their importance. The first set will be used to identify potential concerns and trigger a response from us. The second set includes a wider range of information, including nationally comparable data, which we will check if any of the first set signal concerns. The third set will be used to test and improve the others

and may include analysis which is not routinely available.

Our three sets of indicators

▶ The first set of indicators (see figure 3 on page 25) will be the centrepiece of our new model. It will include data and evidence such as mortality rates, never events, specific results from the national NHS staff and patient surveys, information from whistleblowers, information from individual members of the public who make complaints, raise concerns and provide feedback, and information from Quality Surveillance Groups.

▶ They have been selected because they are things that have a high impact on people and because they can alert us to changes in those areas. An example of a trigger would be higher than expected deaths for people who have had operations that would not normally carry that level of risk. We have set out some examples of possible indicators for mental health services in table 1 on page 26.

▶ Any indicator in this set which points to a potential concern or a decline in quality over a period of time will trigger questions from us. Our response will vary depending on the concern. For example we may ask the trust responsible for the hospital for more information and explanation; we may carry out an inspection; or in extreme cases we may suspend a service.

▶ The indicators are used to pursue lines of enquiry; regulatory judgements leading to ratings will take place only after any inspection has been carried out.

▶ We will also make sure that we explore the full potential of the results of the 'Friends and Family Test', which asks people how likely they are to recommend a ward or A&E department to friends and family if they needed similar care or treatment to assess quality.

How will we use people's experiences of services?

The reality of people's experiences of care will be a key source of information for CQC. As well as being a core focus of our inspections, we will use people's experiences to help determine which hospitals and services we will inspect and the issues that we will follow up on inspection. We will analyse individual patient experience alongside the national survey programme and Friends and Family Test. Sources include:

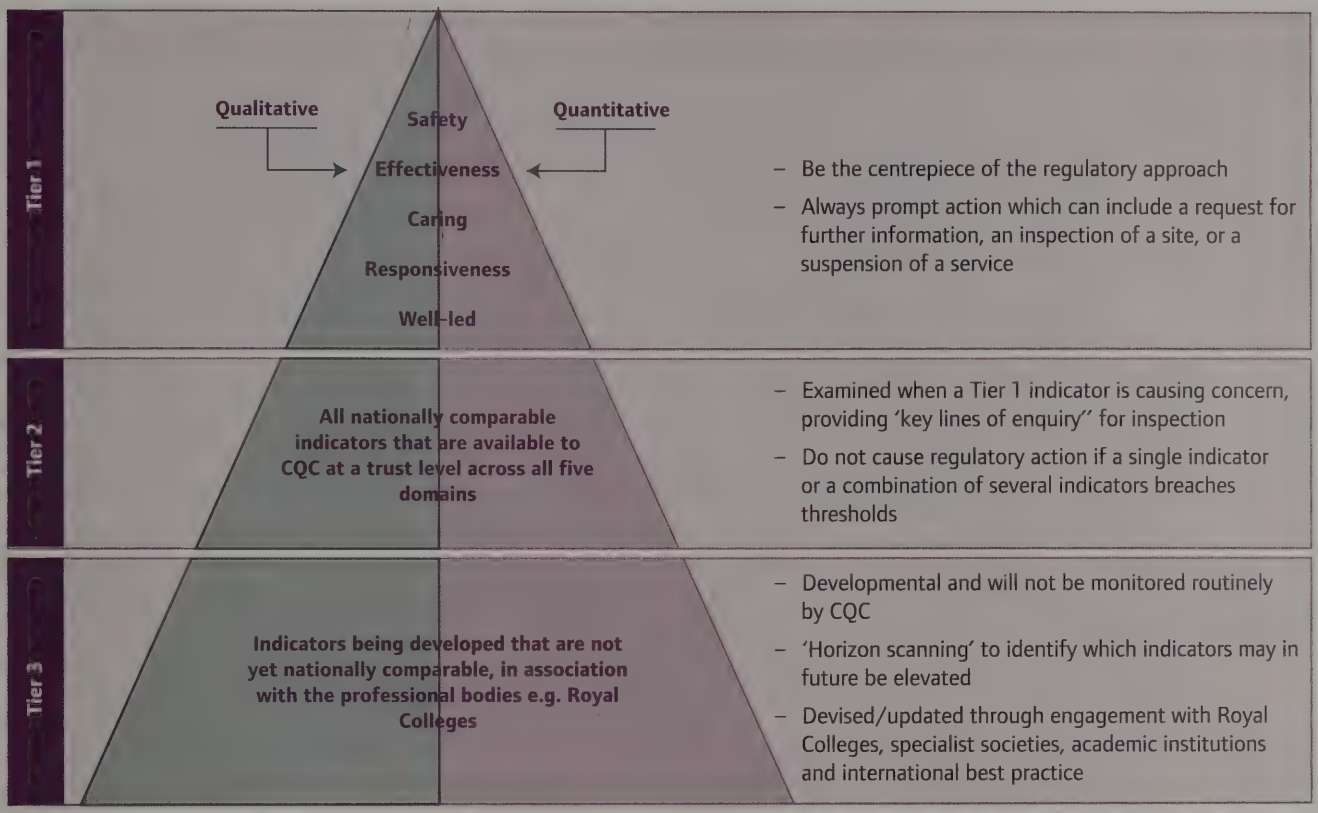
- Healthwatch England recommendations
- Complaints investigated by the Ombudsman
- Number and themes of complaints made to CQC's National Customer Service Centre
- Share Your Experience comments submitted via CQC's website
- Comments posted on NHS Choices and Patient Opinion (starting with negative comments)
- Experiences shared through patient organisations
- Concerns raised directly by staff.

▶ The second set of indicators will include a much wider range of intelligence which on their own may not trigger action by us. We will check them if the first set of indicators signal a concern, to help understand the issues raised and decide what an inspection should focus on. This second set of indicators will include nationally comparable data such as results from National Clinical Audits, admission profiles for each NHS trust, wider sets of patient and survey results, and information from accreditation schemes.

▶ The third set will include indicators that are not yet nationally comparable, are not routinely available or which are the result of 'one-off' data collections. We will use this set to horizon scan for those indicators which may be useful in the future as part of the first or second set of indicators.

▶ While we have grouped our indicators around the five main questions we will ask about services, we recognise that many indicators will cut across more than one of those questions – for example comments submitted via the 'Share Your Experience' form on CQC's website.

FIGURE 3: INDICATORS TO TRIGGER ACTION IN OUR REGULATION AND INSPECTION OF ACUTE HOSPITALS



▶ We will refine these indicators through this consultation and engagement and by scanning new information sources and refining our analysis. We would welcome views on the proposed indicators and intelligence.

▶ We will apply the same approach to NHS mental health trusts, community health trusts and ambulance trusts and will consider how the methodology can best be applied to social care, independent healthcare and primary care providers. We know that for certain organisations and sectors there is less national data available – and we will take this into account as we design how we make the best use of intelligence for these sectors. We will consult on our proposals for each type of organisation as they are developed.

▶ Please see the annex to this consultation for our proposals for the first set of indicators for NHS acute hospitals. For illustrative purposes only we have set out some examples of possible indicators in table 1, focusing on one of the five questions: Is the trust safe?

TABLE 1: ILLUSTRATION OF POTENTIAL SAFETY INDICATORS FOR ACUTE AND MENTAL HEALTH TRUSTS

Dimension	Acute NHS trusts	Mental health trusts
Rate of deaths is higher than expected	Deaths of people who have low risk conditions Deaths of people who have undergone low risk procedures (e.g. hernia repair)	Deaths of people in contact with the service Deaths of people who are detained in hospital under the Mental Health Act
Never events*	Includes for example: A surgical intervention performed on the wrong site Surgical instrument unintentionally retained after an operation In-hospital death of a mother as a result of a haemorrhage following an elective caesarean section	For example: Suicide using curtain or shower rails by an inpatient in an acute mental health setting A patient who is a transferred prisoner escaping from medium or high secure mental health services where they have been placed for treatment on a Home Office restriction order
Reporting of incidents	Lower reporting than expected of key safety incidents	Lower reporting than expected of key safety incidents Severe harm as a result of restraint where practice has not complied with the Mental Health Act Code of Practice
Avoidable infections	Avoidable infections – e.g. C.difficile and MRSA	

* Never events are preventable patient safety incidents that should not occur if the available preventative measures have been implemented.

▶ We are committed to being transparent about how we will monitor services and we will share the analyses with NHS trusts, commissioners and other regulatory bodies in the health and social care system. However we want to place as much information in the public domain as possible. We would therefore welcome feedback on how much of the information and analysis used in our monitoring model we should make public as a matter of routine.

Changes to how we inspect NHS and independent acute hospitals

▶ The Chief Inspector will lead teams of specialist hospital inspectors, clinical and other experts who will carry out inspections on a rolling basis.

Planning an inspection

▶ Before carrying out any inspection, our inspectors will review all the information we hold about a hospital, plan which parts of the hospital they will inspect, and bring together the independent experts they need to make up their inspection team. For example, they may include clinical consultants, directors of nursing, chief executives or board members of other hospitals, and trained members of the public who have a lot of experience of hospital care. Some of the inspection team will be CQC employees, others will be independent experts who join our teams for a certain number of days each year. The teams will vary in size but will usually be bigger than they are now.

▶ Our inspectors will decide whether or not to tell the hospital that they are coming. Currently all of our inspections are unannounced so that the hospital cannot prepare for our visit. This can make it more difficult to speak to people in the local community or to set up discussions with staff beforehand. In future, whether or not we let the hospital know we are coming will depend on what we are inspecting and why. For example, inspections to follow up on whether improvements have been made will mostly be unannounced; inspections in response to serious concerns may be unannounced in the first instance but we may go back to speak to more staff, managers, patients and others and we will let them know in advance. Our expectation is that the majority of inspections will remain unannounced.

Carrying out inspections

▶ Our inspections will be carried out on a rolling basis and will look at whether or not services are:

- Safe
- Effective
- Caring
- Responsive to people's needs
- Well-led.[3]

▶ How often we carry out inspections will vary based on each hospital's performance. We will inspect as often as is needed to follow up on any concerns and to make sure the rating is up to date. We will inspect at weekends or during the night where we think it is needed. A hospital with a lower rating will be inspected more often than a hospital with a higher rating.

▶ Our new hospital inspection teams will also carry out targeted inspections in response to serious concerns identified by CQC, our partners in the system or the public. These inspections may focus on particular services, clinical areas or aspects of care.

▶ We will also carry out inspections which look at particular types or aspects of care across all services – for example care of people with dementia.

▶ Our inspections of hospitals will vary in terms of the things they look at and the time they take, but they will take as long as is needed – typically 15 days, with an average of 6-7 days on site – to make a thorough assessment of the quality and safety of care. In the vast majority of cases, inspections will be longer and more thorough than our current approach of a small team of inspectors being on site for one or two days. Our inspectors will spend more time talking to people who use the service, to staff, senior managers and members.

▶ Some of our inspections will remain shorter and more focused. For example, if we need to follow up on a particular area of concern we would inspect for less time and with a smaller team.

▶ The inspection judgements that we make from October 2013 and any ratings that we publish before April 2014 will be based on our new framework of expected standards and fundamentals of care. However, because the new framework and supporting guidance will not be underpinned by changes to Regulations until April 2014, any action that we take will be taken using our existing framework. We will explain more about how we will do this later this year.

Working with others

▶ We are looking at how we will work with other organisations in our inspections of acute hospitals. Other organisations visit hospitals and assess the quality of services, including accreditation schemes such as those awarded by Royal Colleges or other specialist organisations. These tell us a great deal about the quality of services.

▶ We are considering:

- Drawing on the evidence that other organisations such as the Medical Royal Colleges gather through clinical audits or peer review and asking them to carry out visits on our behalf that would look at particular aspects of care. We would work with these

3. Our assessments of 'well-led' in acute hospitals will focus on quality, not financial governance, which is part of the role of Monitor and the NHS TDA.

organisations to develop how this would work in more detail.

- Involving experts from other organisations to join our inspection teams to advise on what we should be looking at and what is best practice in particular areas of care.
- Using the findings of other organisations that carry out clinical audits and accredit hospitals as evidence that would contribute to a hospital's rating or help us decide when, where and what to inspect.

▶ Our Chief Inspector of Hospitals will make sure we make the most of 'peer review' – the findings and opinions of other experts – in our findings.

▶ Our teams will share information about the hospitals in their area with local partners, including commissioners, professional regulators, local Healthwatch, lead Quality Surveillance Groups, local authorities, health and wellbeing boards, overview and scrutiny committees and others. They will also share information with others who have insight into people's experiences of the quality and safety of care locally, including local MPs. They will make sure that people's views and experiences of care are a top priority for all.

The action we will take to tackle poor care

▶ As described in *Patients First and Foremost* the government intends to introduce a single failure regime that will place the same emphasis on addressing failures in quality of care as there is on financial failure.

▶ As part of this, the action we will take to identify and tackle serious problems with poor care in NHS trusts and NHS foundation trusts will have three phases. It may be triggered by a specific incident but can equally be a consequence of a trust being in either of the bottom two rating categories.

▶ Firstly, if the Chief Inspector of Hospitals believes that a trust requires significant improvement, the board of the trust will be issued with a warning notice which requires them to improve within a fixed time period.

▶ Secondly, if the trust and those who commission its services are unable to resolve the problems themselves, the Chief Inspector will formally request Monitor or the NHS Trust Development Authority (NHS TDA) to take action to protect people, to deal with the failure, and to hold individuals to account. For example, Monitor or the NHS TDA may bring in expert clinical support to make the improvements. We would consider this as equivalent, for the trust concerned, to the 'special measures' that Ofsted operate for schools.

▶ Lastly, if care still fails to improve, the Chief Inspector, through CQC will be able to direct Monitor or NHS TDA to appoint a special administrator, suspending the board of the trust as a result. Special administration will provide a framework for determining how best to secure a comprehensive range of high-quality services that are sustainable in the long term.

▶ In the event of closure of services, the provider and Monitor or the NHS TDA will work with NHS England and local clinical commissioning groups to make sure that local people have access to alternative safe, high-quality hospital care.

▶ In all these cases, it is for Monitor and the NHS TDA together with the provider to decide what action is needed to improve the service. CQC will judge if the action has been effective in improving the quality of care.

▶ We will begin to introduce this programme from October 2013 through a protocol setting out how CQC, Monitor and NHS TDA will coordinate our respective powers of intervention. It will be underpinned by legislation when the Care Bill completes its Parliamentary passage.

▶ CQC will retain the ability to stop a service from providing care if it if is putting people at immediate risk of harm. We are also working with Monitor and the NHS TDA to make sure there are clear procedures for acting on less urgent concerns.

Below is an example of how this might work in practice.

Phase 1

▶ CQC becomes aware of a number of complaints about local emergency care services at an NHS non-foundation trust and certain key indicators of effectiveness are dropping. CQC shares these with local partners and the NHS TDA, and decides to bring forward its inspection and finds that emergency services are poorly managed and poorly led. The emergency department feels and looks far too busy and hygiene procedures are not always observed; junior doctors are regularly working above their rostered hours; frontline staff can be rude to patients due to strain and overwork; and there are concerns that although the situation is not dangerous, the service is not as effective as it could be.

▶ As a result the Chief Inspector of Hospitals judges that emergency services are not meeting expected standards of care. These findings are shared with NHS TDA and commissioners, who request the trust improve and provide support.

▶ While exploring the concerns about emergency services, the Chief Inspector identifies further concerns about the capacity of management at the trust and the Board to monitor effectively the quality of the services provided across the trust. As a result of these concerns the trust is issued with a warning notice and is given six months to make the significant improvements required. Working with commissioners, it develops an action plan to address the quality failures. The judgement of the inspection is that the hospital should be rated 'Requires Improvement'.

Phase 2

▶ CQC inspects the A&E service again, on a Saturday night. The situation has not improved. Patients complain about having to wait a long time and the rudeness of the staff; a number of key personnel, such as consultants, have left or are planning to leave; the management team has not stopped services getting worse and acknowledge that they are struggling to bring about the required improvements. CQC also now has concerns about emerging problems in the Medical Assessment Unit where it is difficult to find suitably capable staff to cover weekends and nights.

▶ A local risk summit is convened, and confirms a number of concerns and no plan that commands confidence to deal with them. CQC judges that the necessary improvements have not been made to the quality of A&E care. Further intervention is now required and CQC formally requests the NHS TDA to do so.

▶ The NHS TDA considers what further intervention is needed to make sure improvements are made. As part of this they review the skills and competences of executive and non-executive board members and decide to bring in short-term support to the management team, liaising with CQC.

Phase 3

▶ A further CQC inspection in six months' time reveals that improvements have still not been made. The NHS TDA decides whether or not the Secretary of State should be advised to place the trust into special administration to address the serious problems at the trust (this would include suspension of the board) and to consider options for securing long-term, high-quality services.

Ratings for NHS acute hospitals

▶ Earlier in this document, we set out our proposal to begin publishing ratings for NHS trusts from December 2013.

▶ Ratings for NHS trusts and NHS foundation trusts will be based primarily on inspection judgement, and informed by a series of indicators, using data already available and the findings of others. The findings of others could be accreditation schemes, clinical peer review as well as the judgments of other regulators. We will consult on these proposals in detail later in the year.

▶ We will produce ratings and the information on which the ratings are based at a level which recognises the complexity of NHS services and is useful to people who use services as well as those who provide and commission NHS care. We are therefore proposing to provide ratings for certain

individual services (for example, emergency or maternity services) as well as each hospital. We would also like to provide ratings for each of our key questions – is the service:

- Safe?
- Effective?
- Caring?
- Responsive to people's needs?
- Well-led?

▶ This would mean that, where sufficient evidence was available, a trust would have five ratings each at the level of an individual service, a hospital, and the whole trust. We would welcome people's views on how this could work and whether this would be useful or overly complex.

Rating	Description of trust and hospital rating	Description of a service level rating
Inadequate*	Serious and systemic failings in relation to quality, and fundamentals of care are not met on an ongoing basis across multiple domains. Urgent intervention is required.	Serious and systemic failings in relation to quality, and fundamentals of care are not met on an ongoing basis across multiple domains. Urgent intervention is required.
Requires improvement	Fundamentals of care are breached and/or Services across the provider may not be meeting expected standards in one or more domain. Significant action by the provider is required to address the problem.	Fundamentals of care are breached and/or expected standards are not being met in one or more domain. Significant action by the provider is required to address the problem.
Good	No fundamentals of care breaches **or** rare occurrence of breaches are acted on quickly and effectively by the provider. Care is generally judged as good and the majority of services are meeting expected standards and high-quality standards. No inadequate services.	No fundamentals of care breaches. Any breaches in expected standards in any domain (not fundamental) are acted on quickly and effectively by the provider. Care is generally judged as good. There is evidence that the service is meeting high-quality standards.
Outstanding	No fundamentals of care breaches. No inadequate services with most services rated as 'Good' or 'Outstanding'. Any breaches in expected standards (not fundamental) are acted on quickly and effectively by the provider. There is a range of evidence that the service is sustaining high-quality care** over time across most services in the organisation. There is evidence of innovation. No governance or finance issues from Monitor or NHS TDA.	No fundamentals of care breaches. All expected standards across all domains are met. There is a range of evidence the service is sustaining high-quality care** over time across most specialities. There is evidence of innovation.

* If an acute hospital is in phase 2 of the programme for failing NHS hospitals, it will be judged to be in the equivalent to what Ofsted term 'special measures', in addition to its inadequate rating.

** For example consistently meeting NICE quality standards or Royal College standards through clinical peer review

Ratings scale

▶ We propose issuing ratings of services, hospitals and trusts, and of our five key questions, on a four-point scale.

▶ The proposed ratings scale reflects principles we will apply in response to providers not meeting expectations and how we recognise excellence in 'outstanding' organisations. Judgements against each of our five questions will be treated equally, and services and hospital ratings will be aggregated into a single organisational level rating.

▶ When there are breaches of the fundamentals of care, we will not consider them in isolation. We will consider if the breach occurred as a result of isolated human error or because of a systemic failure within a service, hospital or organisation (for example, inadequate staffing levels). We will also look at the speed and quality of the response of the provider and its staff to the breach and the impact of that response to determine how this should be reflected in ratings at service, hospital and organisational level. We expect breaches of the fundamentals of care in 'good' trusts to be the result of isolated human error and recognise the need to be proportionate in such circumstances. We will ensure our judgements of these cases will be clear and transparent.

▶ We also propose that a 'good' trust may still retain its organisational ranking with a low number of services 'requiring improvement', but only if fundamentals of care breaches do not reflect systemic failure and we have confidence in the response of the provider. 'Outstanding' organisations must be able to demonstrate the sustained delivery of high-quality care across the majority of services and demonstrate innovation. You cannot be an outstanding trust if you have breached the fundamentals of care.

Issuing and reviewing a rating

▶ From October 2013, CQC will start to inspect and regulate NHS acute hospitals in the ways set out in this document. From December 2013 we will begin to rate NHS acute trusts and NHS foundation acute trusts, aiming to complete them before the end of 2015 .

▶ We will inspect 'outstanding' hospitals every 3-5 years; 'good' hospitals every 2-3 years; hospitals where 'improvements are required' at least once a year, and those rated as 'inadequate' as and when needed.

▶ Our monitoring of NHS hospitals could identify concerns which trigger inspections at any time and this could lead to a review of the rating. The outcome of a review may be that the rating is judged a fair reflection of quality and safety, that the inspection is not broad or in-depth enough to change the overall rating or that the rating needs to be changed. Ratings are more likely to be reviewed where systemic poor practice is found, or if a recurring problem is not satisfactorily resolved. Therefore, not all inspections will result in a rating being issued or changed.

▶ We will develop a formal rules-based methodology to determine when a rating should be changed based on our evidence and judgement.

Consultation questions

Intelligent monitoring of NHS acute hospitals

7. Do you agree with the proposals for how we will organise the indicators to inform and direct our regulatory activity?

8. Do you agree with the sources we have identified for the first set of indicators? Please also refer to the annex to this consultaiton.

9. Which approach should we adopt for publishing information and analysis about how we monitor each NHS trust? Should we:

   - Publish the full methodology for the indicators?
   - Share the analysis with the providers to which the analysis relates?
   - Publish our analysis once we have completed any resulting follow up and inquiries (even if we did not carry out an inspection)?

Inspections

10. Do you agree with our proposals for inspecting NHS and independent acute hospitals?

Ratings

11. Should the rating seek to be the 'single, authoritative assessment of quality and safety'? Although the sources of information to decide a rating will include indicators and the findings of others, should the inspection judgement be the most important factor?

12. Should a core of services always have to be inspected to enable a rating to be awarded at either hospital or trust level?

13. Would rating the five key questions (safe, effective, caring, responsive and well-led) at the level of an individual service, a hospital and a whole trust provide the right level of information and be clear to the public, providers and commissioners?

14. Do you agree with the ratings labels and scale and are they clear and fair?

15. Do you agree with the risk adjusted inspection frequency set out which is based on ratings, i.e. outstanding every 3-5 years, good every 2-3 years, requires improvement at least once per year and inadequate as and when needed?

General

16. The model set out in this chapter applies to all NHS acute trusts. Which elements of the approach might apply to other types of NHS provider?

Please also see the questions in the annex to this consultation.

Section 4: Changes to CQC's regulations

CQC's registration requirements are set out in secondary legislation, known as regulations. These regulations give CQC the legal power to register, judge and take action against those who provide and manage care.

This section sets out proposals by the Department of Health and CQC for making changes to those regulations to underpin CQC's new operating model.

This section of the consultation document **applies to all providers registered by CQC**.

There are three main changes to CQC's regulations:

▶ The introduction of fundamentals of care, and other organisational requirements about providers, as CQC registration requirements. The registration requirements will be simpler, and fewer in number, than the current CQC registration requirements which they will replace. We also aim to make it simpler to prosecute providers when these fundamentals of care are breached.

▶ The introduction of a statutory duty of candour as one of the organisational requirements on all providers registered with CQC, fulfilling the commitment made in *Patients First and Foremost*.

▶ Strengthening the powers to hold to account providers that allow unacceptable standards of care to occur, responding in particular to the events at Winterbourne View, but also at Mid Staffordshire. The Department of Health will publish a separate consultation shortly that will set out in detail the proposed changes, including the introduction of a new fit and proper persons test for directors of boards.

Turning the fundamentals of care into registration requirements

▶ Section 2 set out how changes will be made to the registration requirements so that they establish a clear baseline below which standards of care must not fall. Following this consultation, the Department of Health will publish regulations in draft during the autumn for further discussion. These will then be debated in Parliament, and the aim is to enact them in secondary legislation in April 2014.

▶ The new legislation will aim to allow CQC to prosecute breaches of the fundamentals of care without the need to issue a warning notice. This new power will sit alongside CQC's other existing powers of intervention, such as a clear programme for failing NHS trusts and the range of civil enforcement powers for all other providers.

Duty of candour

▶ Those who provide care services should tell people who use the service and their families about any problems that have affected the quality and safety of the care, and explain why they have happened. A contractual duty of candour was introduced into NHS contracts from April 2013 and in *Patients First and Foremost* the government committed to a statutory duty of candour on health and social care providers. A spirit of candour is vital to ensuring that problems are identified and dealt with quickly. A requirement to be open already exists in the professional codes of practice for managers, doctors and nurses. It is already the responsibility of boards in provider organisations to support openness. This approach was not apparent at Mid Staffordshire.

▶ The government intends to introduce a statutory duty of candour as a CQC registration requirement on all health and social care providers. It will require providers to make sure staff and clinicians are open with people who use services and their families where there are failings in care and to provide an explanation for it. This will underline the importance of transparency, openness and candour, and provides a mechanism for making sure that all of the provider's employees act in accordance with the duty.

▶ The registration requirement should be sufficiently clear that CQC could prosecute an organisation without having to issue a warning notice. The new registration requirement should mean CQC can take action against a provider that was not open with people who use services about failings in care.

Consultation questions

Duty of candour

17. Do you agree that a duty of candour should be introduced as a registration requirement, requiring providers to ensure their staff and clinicians are open with people and their families where there are failings in care?

18. Do you agree that we should aim to draft a duty of candour sufficiently clearly that prosecution can be brought against a health or care provider that breaches this duty.

19. Do you have any other comments about the introduction of a statutory duty of candour on providers of services via CQC registration requirements?

Section 5: Consultation questions

This section repeats the consultation questions we have asked throughout this document.

How to respond to this consultation

You can give us your views and comments by post, email or on our website using the addresses below, by **Monday 12 August 2013**.

Section 2

General

1. What do you think about the overall changes we are making to how we regulate? What do you like about them? Do you have any concerns?
2. Do you agree with our definitions of the five questions we will ask about quality and safety (is the service safe, effective, caring, responsive and well-led)?

Fundamentals of care

3. Do you think any of the areas in the draft fundamentals of care above should not be included?
4. Do you think there are additional areas that should be fundamentals of care?
5. Are the fundamentals of care expressed in a way that makes it clear whether they have been broken?
6. Do the draft fundamentals of care feel relevant to all groups of people and settings?

Section 3

Intelligent monitoring of NHS acute hospitals

7. Do you agree with the proposals for how we will organise the indicators to inform and direct our regulatory activity?
8. Do you agree with the sources we have identified for the first set of indicators?
9. Which approach should we adopt for publishing information and analysis about how we monitor each NHS trust? Should we:
   - Publish the full methodology for the indicators?
   - Share the analysis with the providers to which the analysis relates?
   - Publish our analysis once we have completed any resulting follow up and inquiries (even if we did not carry out an inspection)?

Inspections

10. Do you agree with our proposals for inspecting NHS and independent acute hospitals?

Ratings

11. Should the rating seek to be the 'single, authoritative assessment of quality and safety'? Although the sources of information to decide a rating will include indicators and the findings of others, should the inspection judgement be the most important factor?
12. Should a core of services always have to be inspected to enable a rating to be awarded at either hospital or trust level?
13. Would rating the five key questions (safe, effective, caring, responsive and well-led) at the level of an individual service, a hospital and a whole trust provide the right level of information and be clear to the public, providers and commissioners?
14. Do you agree with the ratings labels and scale and are they clear and fair?
15. Do you agree with the risk adjusted inspection frequency set out which is based on ratings, i.e. outstanding every 3-5 years, good every 2-3 years, requires improvement at least once per year and inadequate as and when needed?

General

16. The model set out in this chapter applies to all NHS acute trusts. Which elements of the approach might apply to other types of NHS provider?

Section 4

Duty of candour

17. Do you agree that a duty of candour should be introduced as a registration requirement, requiring providers to ensure their staff and clinicians are open with people and their families where there are failings in care?
18. Do you agree that we should aim to draft a duty of candour sufficiently clearly that prosecution can be brought against a health or care provider that breaches this duty.
19. Do you have any other comments about the introduction of a statutory duty of candour on providers of services via CQC registration requirements?

The following questions relate to the Impact Assessments that accompany this document.

Impact Assessments

20. Do you have any comments on the draft Regulatory Impact Assessment?
21. Do you have any comments on the draft Equality and Human Rights Duties Impact Analysis?

The following questions are set out in the separate Annex – *Proposed model for intelligent monitoring and expert judgement in acute NHS trusts*

A1. Do you agree with the principles that we have set out for assessing indicators?

A2. Do you agree with the indicators and sources of information?

A3. Are there any additional indicators that we should include as 'tier one' indicators?

A4. Do the proposed clinical areas broadly capture the main risks of harm in acute trusts? If not, which key areas are absent?

A5. Do you agree with our proposal to include more information from National Clinical Audits once it is available?

A6. Do you agree with our approach of using patient experience as the focus for measuring caring?

How to respond to this consultation

You can respond to our consultation in the following ways. Please send us your views and comments by **Monday 12 August 2013**.

Online

Use our online form at:
www.cqc.org.uk/inspectionchanges

By email

Email your response to:
cqcinspectionchanges@cqc.org.uk

By post

Write to us at:

CQC Inspection Changes
CQC National Customer Service Centre
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Please contact us if you would like a summary of this document in another language or format.

Care Quality Commission

How to contact us

Call us on: **03000 616161**

Email us at: **enquiries@cqc.org.uk**

Look at our website: **www.cqc.org.uk**

Write to us at: **Care Quality Commission**
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

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